POSTINOR[®]-1 levonorgestrel CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Postinor-1. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist will have discussed and considered the risks of you taking Postinor-1 against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Your doctor and pharmacist have more information

Keep this leaflet with the medicine.

You may need to read it again.

What Postinor-1 is used for

Postinor-1 is an emergency contraceptive only. Postinor-1 is not intended as a regular method of contraception. It is used to prevent pregnancy when taken within 72 hours of unprotected intercourse. It is estimated that Postinor-1 will prevent 85% of expected pregnancies. The sooner that you take Postinor-1 after unprotected intercourse, the more likely it is that the medication will work. Emergency contraception does not prevent a pregnancy in every instance

Postinor-1 will not prevent you from catching sexually transmitted diseases. Ask your doctor or pharmacist if you have any questions about why you are taking Postinor-1.

Before you take Postinor-1

Before you start treatment with Postinor-1, your doctor or pharmacist should:

Check you are not already pregnant if he/she suspects you may already have been pregnant before this occurrence of unprotected intercourse

Ask you if you are taking any other medicines (see *Taking other medicines*)

Ask if you suffer from high blood pressure

Advise you of the need for careful use of a barrier method of contraception until you have your next period

 $\hfill\square Advise you to see your doctor in three weeks time, especially if you have not had a period by then$

Discuss the need for regular contraception

You should consult your doctor before you take it if:

☐You have diabetes mellitus (with kidney, eye or nerve damage, or vascular disease) – Diabetes mellitus is a condition in which the body does not produce enough insulin or else the body tissues are not able to use the insulin present. This leads to hyperglycaemia (too much sugar in the blood)

☐You have ischaemic heart disease (heart disease caused by reduced blood flow in the blood vessels of the heart muscle)

☐You have suffered a stroke

□You have had breast cancer

☐You have severe liver disease

If any of these conditions apply to you it may not be suitable for you to take Postinor-1

□you have a disease of your gastro-intestinal tract (such as Crohn's disease) that interferes with the digestion and absorption of your food;

□you are vomiting or have severe diarrhoea

If these conditions apply to you your doctor may recommend a higher dose.

When you must not take it

Do not take Postinor-1 if:

□You are pregnant

You have previously had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, as you may already be pregnant

□You are experiencing vaginal bleeding for which the reason is not known

☐You have breast cancer

□You are allergic to any of the ingredients of the tablets (See Product Description below)

The tablets do not look quite right

Do not take Postinor-1 after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including those purchased from a supermarket or health food store. Some medicines may prevent Postinor-1 from working properly or Postinor-1 may affect the way other medicines work. Examples of medicines which may interfere with Postinor-1 are:

- Medicines used to treat epilepsy (for example, barbiturates, primidone, phenytoin, and carbamazepine).

- Medicines used to treat tuberculosis (for example, rifampicin, rifabutin).

- A treatment for HIV infection (ritonavir).

- A medicine used to treat fungal infections (griseofulvin).

- Herbal remedies containing St John's wort (Hypericum perforatum)

- A medicine used to treat transplant rejection, rheumatoid arthritis, atopic dermatitis, kidney disorders or inflammation of the eye (ciclosporin)

How to take Postinor-1

Take the tablet as soon as possible after unprotected intercourse. The sooner that you take the tablet, the more effective the treatment is likely to be. It is best to take it immediately after you receive it. The tablet should be taken no later than 72 hours after intercourse. There is some evidence that Postinor-1 may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, Postinor-1 is still recommended for all women regardless of their weight or BMI.

Postinor-1 is not recommended for children. There is only limited information available on Postinor-1 when taken by women aged 14-16 years and no information on its use in younger women or children.

While taking Postinor-1

If you vomit within 3 hours of taking the tablet you should return to your pharmacy, doctor or clinic as the tablet may not be absorbed and you will need to take an additional tablet.

Things you must do

Tell any doctor or pharmacist who are treating you that you have taken Postinor-1

Things you must not do

Do not give Postinor-1 to anyone else

Things to be careful of

If Postinor-1 makes you drowsy or dizzy, do not drive a car or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after you take Postinor-1.

All medicines have side effects. Often they are not serious but sometimes they can be. You may need medical treatment if you get some side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Common side effects are tiredness, nausea and vomiting. Some patients have also experienced stomach pain, diarrhoea, dizziness, headache, tender breasts and increased vaginal bleeding.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using Postinor-1

You should see your doctor within 3 weeks of taking Postinor-1.

You may experience spotting or vaginal bleeding earlier than expected.

If you do not get your period within 3 weeks of taking the tablets you must see your doctor, as you may be pregnant. If Postinor-1 does not work, you could be pregnant. Your doctor will order a pregnancy test. If stomach pain is severe you should see your doctor immediately as on rare occasions a tubal pregnancy could occur.

Postinor-1 is only intended as an emergency measure. If you have not already done so you should discuss with your doctor other methods of long term contraception.

You should not breast feed within three days after taking Postinor-1.

If you take too much (Overdose)

Telephone your doctor, or the Poisons Information Centre (13 11 26 in Australia or 0800 764766 in New Zealand) if you take too many Postinor-1 tablets, or if a child has taken Postinor-1.

Product description:

Postinor-1 contains one blister sheet containing one flat white tablet. The tablet contains 1.5 milligrams of levonorgestrel and the following inactive ingredients: potato starch, maize starch, silica colloidal anhydrous, magnesium stearate, talc, lactose.

Storage:

Keep your tablet in the pack until it is time to take it. If you take the tablet out of the pack it will not keep well.

Keep your tablet in a cool, dry place where the temperature stays below 25 C.

Do not store Postinor-1 or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children can not reach it.

A locked cupboard at least 1¹/₂ metres above the ground is a good place to store medicines.

The expiry date is printed on the pack and the foil blister. Do not use Postinor-1 after this expiry date.

Where to go for further information

If you require further information you should contact your pharmacist, doctor or clinic.

Additional information is also available at the website: www.emergencycontraception.com.au

Supplier:

The sponsor for Postinor-1 in Australia is: Affordable Generics Pty Ltd 11 Cornwell Road, Allambie, NSW 2100 Australia

and in New Zealand is: Rex Medical Ltd PO Box 18-119 Glen Innes AUCKLAND

The distributor for Postinor-1 in Australia is: Bayer Australia Limited 875 Pacific Highway Pymble, NSW, 2073

and in New Zealand is: Bayer New Zealand Limited 3 Argus Place Hillcrest North Shore AUCKLAND 0627

The AUST R Number for Postinor-1 is 149269 ®Registered Trademark.

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